



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0001]

Facilitating Anti-infective Drug Development for Neonates and Young Infants; Notice of Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop regarding anti-infective drug development for neonates and young infants. FDA is interested in discussing the scientific challenges pertaining to development of anti-infective products for neonates and young infants. This public workshop is intended to provide information for and gain perspective from health care providers, other U.S. Government Agencies, public health organizations, academic experts, and industry on various aspects of drug development for new and currently marketed anti-infective drugs for neonates and young infants. The input from this public workshop will also help in developing topics for future discussion.

DATE: The public workshop will be held on September 15, 2016, from 8:30 a.m. to 4:30 p.m.

See the SUPPLEMENTARY INFORMATION section for registration information.

ADDRESSES: The public workshop will be held at the Sheraton Silver Spring Hotel, 8777 Georgia Ave., Silver Spring, MD 20910. The hotel's phone number is 301-589-0800.

FOR FURTHER INFORMATION CONTACT: Lori Benner and/or Jessica Barnes, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6221, Silver Spring, MD 20993-0002, 301-796-1300.

SUPPLEMENTARY INFORMATION: FDA is announcing a public workshop regarding anti-infective drug development for neonates and young infants. Discussions will focus on challenges related to enrolling neonates and young infants in clinical trials, strategies to assess central nervous system (CNS) penetration of the drug, including nonclinical and in vitro data, potential development pathways, and the role of clinical trial networks in anti-infective drug development in the neonatal population.

Registration: Registration is free for the public workshop. Interested parties are encouraged to register early. Seating will be available on a first-come, first-served basis. To register electronically, email registration information (including name, title, firm name, address, telephone, and fax number) to NeonatalAntibacterialWorkshop2016@fda.hhs.gov. Persons without access to the Internet can call 301-796-1300 to register.

If you need special accommodations due to a disability, please contact Jessica Barnes or Lori Benner (see FOR FURTHER INFORMATION CONTACT) at least 7 days in advance.

Agenda: The workshop draft Agenda will be made available at: <http://www.fda.gov/Drugs/NewsEvents/ucm507958.htm> at least 2 days prior to the meeting. The Agency encourages individuals, industry, health care professionals, researchers, public health organizations and other interested persons to attend this public workshop.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on the Agency's Web site at <http://www.fda.gov>. Transcripts will also be

available on the Internet at: <http://www.fda.gov/Drugs/NewsEvents/ucm507958.htm>
approximately 45 days after the workshop.

Dated: August 8, 2016.

Jeremy Sharp,

Deputy Commissioner for Policy,

Planning, Legislation and Analysis.

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